FDA Issues Interagency Draft Guidance on "Good Importer Practices" and Announces Two New Pilot Programs on Drug Import Safety

With just days to go before the end of the Bush Administration, the Food and Drug Administration (FDA) has issued several significant documents addressing the safety of imported products.

- On January 13, FDA, on behalf of the Department of Health and Human Services and seven other federal government agencies participating in the Interagency Working Group on Import Safety, issued a draft guidance document entitled "Good Importer Practices."[1] Emphasizing the "shared responsibility" between private industry and government in ensuring the safety and legal compliance of imported products, this document recommends practices and procedures for importers to follow in preventing noncompliance and verifying product safety at critical points in the product life cycle. Comments on the draft guidance are due by April 13.
- On January 15, FDA announced a proposed voluntary "Secure Supply Chain" pilot program in which importers of drugs and drug ingredients can choose up to five products that would receive the benefit of expedited entry into the United States if certain supply chain management criteria are satisfied. Comments on the proposal are due by March 16.
- On January 7, FDA, the European Medicines Agency and the Australian Government launched a pilot project to increase coordination of inspection planning and the sharing of inspection results for establishments that manufacture active pharmaceutical ingredients.

Of these three announcements, only the draft guidance on Good Importer Practices applies across all FDA-regulated product areas (as well as other, non-FDA-regulated products). The draft guidance sets forth recommended practices organized under the following four "guiding principles."

1. **Establishing a Product Safety Management Program**. The draft guidance recommends that importers establish a formal Product Safety Management Program that includes a clear management structure and assigned responsibilities for the safety of imported products, including reporting relationships that demonstrate that management places a high degree of importance on import safety. Other suggested features for such a program include establishing written policies, specifications, and procedures to ensure product safety; maintaining records that demonstrate compliance; conducting risk assessments to evaluate risks and control for risks across the product life cycle; and applying a formal quality assurance program to control, monitor, and improve import-related operations.
2. **Knowing the Product and Applicable U.S. Requirements**. The draft guidance states that importers should have a good understanding of the products they are importing, including their specifications and safety concerns, as well as the U.S. regulatory requirements that apply to the products they import, including requirements applicable

[1] President Bush established the Interagency Working Group on Import Safety through Executive Order 13439 (July 18, 2007). In addition to HHS, the other agencies on the working group are the Department of Agriculture, Department of Commerce, Department of Homeland Security, Department of Transportation, Consumer Product Safety Commission, Environmental Protection Agency, and the Office of the United States Trade Representative.

to the manufacturing of such products. Specific recommendations in this area include investigating the reputation of firms involved in the product's life cycle; asking to see official documentation of compliance with U.S. requirements; and knowing whether the production conditions exposed the product to violative chemicals or improper storage conditions.

3. **Verifying Product and Firm Compliance with U.S. Requirements Through the Supply Chain and Product Life Cycle**. Once an importer understands the product and the standards and requirements applicable to it, appropriate measures must be established to verify its compliance with those standards and requirements. The draft guidance provides fairly detailed recommendations on ways in which importers can control, monitor, and verify product and producer compliance prior to arrival of a product in the U.S., during entry of the product into the U.S., and while the product is in U.S. distribution. The recommendations include obtaining written compliance guarantees from suppliers, periodically conducting on-site inspections or paper audits of foreign firms (potentially using independent third parties), and addressing post-importation safety measures such as complaint evaluation, product traceability, quarantine, and recall procedures. Many of these recommendations affect importers' contractual relationships with foreign firms.
4. **Taking Corrective and Preventive Action When the Imported Product or Firm Is Not Compliant With U.S. Requirements**. The draft guidance suggests that importers establish written procedures for developing corrective and preventive action plans that identify the root cause of the non-compliance, require corrective measures that may include re-working, destroying, or exporting a violative product, and require preventive measures such as working with non-compliant firms to meet U.S. requirements or ceasing to do business with them.

The draft guidance sets forth high-level principles applicable across the range of imported products generally. It does not provide targeted guidance for individual product types. While the draft states that government agencies may issue more specific guidance directed at the products they regulate, such category-specific guidance will take time to develop. In the meantime, importers are left with the challenge of developing their own import practices appropriate to their particular circumstances. The nature and extent of appropriate import practices will vary in relation to the hazards posed by different product types and the size and scope of the importing company.

The draft guidance includes numerous statements about importers' responsibilities to assure that foreign firms throughout the product supply chain comply with U.S. law. In light of the tendency of non-binding guidance documents to become de facto standards of care for product liability, contractual liability, and regulatory or even criminal liability purposes, importers should evaluate their practices in light of the recommendation of the draft guidance.

If you have questions about the draft guidance or issues relating to import safety generally, please contact your regular Ropes & Gray legal advisor.